REMARKS

The Office Action mailed May 5, 2003 has been received and carefully considered. Claims 1-47 are currently pending. In the Office Action, the Examiner notes that Claims 1-15 and 17-47 remain rejected as obvious over U.S. Pat. No. 6,335,028 to Vogel et al. ("Vogel"). Claim 16 has been objected to, but has been identified as containing patentable subject matter for which the Applicant expresses appreciation. The amendments do not introduce new issues into the Application and Applicant requests entry of the above amendments, which Applicant submits would put all of the claims of the Application in condition for allowance. Upon entry of the amendments, claims 1-7, 9-20, 23-24, 26, and 28-49 will be pending in the Application. Reconsideration in light of the preceding amendments and remarks which follow is respectfully requested.

I. Amendments to the Claims

Claim 1 has been amended to recite a bio-stable hydrogel comprising about 0.5 to 25% of a polymer, based on the total weight of the hydrogel. The polymer consists essentially of a polymer prepared by combining acrylamide and methylene bis-acrylamide, wherein the biostable hydrogel is in a form suitable for the treatment of incontinence or vesicouretal reflux. The hydrogel includes less than 50 ppm monomeric units.

Claim 9 has been amended to recite a method of treating incontinence or vesicouretal reflux comprising administering a hydrogel to a mammal. The hydrogel comprises about 0.5 to 25% by weight, based on the total weight of the hydrogel, of a polymer prepared by combining acrylamide and methylene-bis-acrylamide. The hydrogel includes less than 50 ppm monomeric units.

Where appropriate, dependent claims have also been amended to correspond to amendments made in claims 1 and 9.

Claims 8, 21, 22, 25 and 27 have been cancelled.

Claims 48 and 49 have been added to further recite various types of incontinence which can be treated by the claimed hydrogel.

II. Paragraph 4 Rejection under 35 U.S.C. 103(a)

Claims 1-15 and 17-47 remain rejected as obvious over Vogel. The Applicant respectfully traverses this rejection.

As stated by the Federal Circuit, "a proper analysis under 35 U.S.C. § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success." *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). In addition, the prior art reference(s) must teach or suggest all of the claim limitations. The teaching or suggestion to combine and the reasonable expectation of success must both be found in the prior art, and not in Applicant's disclosure. *Id* at 493. *See also* M.P.E.P. § 2142.

Vogel does not teach, disclose or suggest a hydrogel as claimed by Applicant. Vogel teaches numerous microparticles/microbeads which are biocompatible non-toxic copolymers coated with, linked to, or filled with agents to promote cell adhesion (cell adhesion promoters). Particularly, the microparticles are microbeads or microspheres having a positive charge on the

surface of the microparticles to treat urinary incontinence, among other afflictions. Col. 5, lines 41-45, 62-64.

Cell adhesion promoters include collagen, gelatin, and other cell adhesion agents. Col. 7 line 65 - Col. 8, line 2. The cell adhesion promoters are introduced in the microbeads by chemical coupling procedures or by diffusion in the gel network of the microparticles, which traps the diffused molecules by precipitation or cross-linking. Col. 8, lines 26-33. As further shown in Examples 1 and 2 of Vogel - Vogel's only examples of the preparation of hydrogel particles which contain acrylamide - gelatin is added to a solution of monomers. After the gelatin is added, N,N,N,N tetramethyl-ethylene-diamine and ammonium persulfate are added. Both of these compounds are identified by Vogel as initiators. Col. 8, lines 45-50. This demonstrates that Vogel teaches hydrogel microparticles which link additional moieties in the hydrogel which are not acrylamide and methylene-bis-acrylamide. Thus, it appears that Vogel's polymer includes a block copolymer of cell adhesion promoters, such as gelatin, and acrylamide. In contrast, Applicant's invention is directed to the use in a hydrogel of a polymer prepared by combining acrylamide and methylene-bis-acrylamide, rather than a block copolymer which incorporates a cell adhesion promoter. Vogel even identifies the adhesion promoters as "monomers" in describing the preparation of microspheres. Col. 8, lines 19-21.

Conversely, the hydrogel in claim 1 of Applicant's invention, and all claims dependent therefrom, requires a hydrogel of 0.5-25% by weight of a polymer which consists essentially of a polymer prepared by combining acrylamide and methylene-bis-acrylamide. Vogel does not teach, disclose, or suggest a hydrogel which comprises a polymer which consists essentially of a

polymer prepared by combining acrylamide and methylene-bis-acrylamide, much less that such a hydrogel would have desirable properties suitable for the treatment of incontinence or reflux.

Vogel can be further differentiated from the hydrogel of claims 1 and 9 and all claims dependent therefrom, in that Vogel teaches away from the claimed invention by suggesting a copolymer that preferably incorporates a monomer having a cationic charge. Col. 7, lines 6-11. These cationic monomers include monomers carrying a tertiary or quaternary amine function. Col. 7, lines 23-27.

As known to those of ordinary skill in the art, a polymer prepared by combining acrylamide and methylene-bis-acrylamide has a neutral charge. Likewise, the claimed hydrogel has less than 50 ppm monomer. Thus, even if any residual monomer were present which might possibly have a cationic charge, as one skilled in the art will appreciate, a residual amount less than 50 ppm would not be sufficient to impart a positive charge to the surface of the hydrogel.

Finally, Applicant submits that Vogel also does not teach a hydrogel in a form suitable for the treatment of incontinence or vesicouretal reflux. In the Office Action, it was stated that Vogel teaches injection of a gel by a syringe as the basis for the assertion that either the form of the hydrogel, or its viscosity, is not a patentable distinction.

Applicant respectfully points out that in Vogel, the hydrogel is not itself injected via a syringe, but the microparticles are first placed in a suspension or formulated into solutions. Col. 6, lines 52-64. As shown further in Examples 13 and 14, both of which describe "Preparations for Injectable Suspensions of Cell-microbeads Particles," the microparticles of Vogel are suspended in serum, preferably at a 1:1 ratio, before injection for treatment. Applicant respectfully submits that as Vogel does not teach, disclose, or suggest injecting the hydrogel

without first suspending the microparticles in solution, Vogel does not teach or suggest all of the limitations of Applicant's claimed invention, which requires that the hydrogel be in a form suitable for treatment of incontinence or reflux.

With respect to U.S. Pat. No. 3,867,329 to Halpern et al., a person of ordinary skill in the art would not necessarily have been motivated to make a polymer of acrylamide cross-linked with methylene-bis-acrylamide as a hydrogel because this polymer could also be produced in dry form.

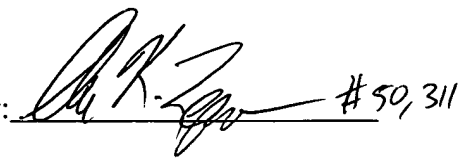
Conclusion

For at least the reasons stated above, entry of the preceding amendments places claims 1-7, 9-20, 23-24, 26, and 28-49 in condition for allowance. Accordingly, Applicant respectfully requests that the amendments be entered and the Application be allowed and passed to issue.

In the event any outstanding issues remain, Applicant would appreciate the courtesy of a telephone call to Applicant's undersigned representative to resolve such issues in an expeditious manner.

Date: October 6, 2003

Respectfully submitted,

By:  #50,311

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